K093014

510 K # 093014 SUMMARY

Prepared: Date 04/15/2010

Submitter Information:

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Contact: George NICOLAE, Ph.D.

Name of the device: American Dental Products BONDEASIER SE SYSTEM

Device Classification: Agent, Tooth Bonding, Resin, (KLE) Class II, 21 CFR 872-3200; 872.3200.

Description.

American Dental Products Bondeasier SE System have the same intended use, perform the same intended function as its predicate device, Bisco's One step.
The subject device is a combination of chemical and light-cured self-etching, self-priming adhesive in a solvent formulation.

Bondeasier SE device is not technique sensitive. It requires painting the tooth surface followed by blowing with air to remove the solvent and placing 1-2 layers of 2-3mm of filled light cure Bondeasier SE Adhesive Resin. Lastly, the final curing of each layer of Bondeasier Adhesive Resin is done with a dental curing light.

It is important to paint the entire area to be bond.
Like any painting, the concentration of the monomers-oligomers is not critical since the solvent-acetone is very volatile and is removed anyway (boiling point 56°C) by blowing air.

I am using the same raw materials that most manufacturers are using from suppliers in the dental industry for more than thirty years and proven safe..

Legally marketed predicate: Bondeasier SE System is substantial equivalent with: Bisco's ONE STEP (k011159) and other dental bonding system (All Bond, All in one, One step plus, Ace Bond SE of Bisco and others) that are on the market since the '80s and '90s.

Intended use:

As a Universal Self-Etching Adhesive Bonding System, BONDEASIER SE SYSTEM is indicated to be used as an universal dental adhesive to etch, prime and bond to a tooth structure and meth(acrylic) dental composite.

Chemical information:

The complete chemical formulation is enclosed with this application.

Bondeasier Acetone solution: contains an acetone solution of a multifunctional methacrylate that will chemically react with the basic tooth structure.

Description of the composition of each component of Bondeasier System:

1. **Bondeasier acetone solution** contains an acetone solution of a multifunctional methacrylate .
2. **Bondeasier resin solution** contains a mixture of methacrylates monomers and photoinitiators mixed in a paste form .

Comparison of technological characteristic to the predicate:

Bondeasier SE system is substantial equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate product Bisco's "One step".
Both products contain in an acetone solution a multifunctional methacrylate ; One step is pre-polymerized with a ten seconds exposure with a dental curing light, and Bondeasier is polymerized with a 30 seconds exposure with a dental curing light after mixing with a resin and copolymerize the entire mixture of the multifunctional methacrylate with the resin mixture.

Discussion of non clinical data:

Side by side bonding tests ran with Bondeasier System and "One step"of Bisco proves that both devices bond to the tooth structure.
The results of the shear bond strength are reported in a tabular form and in details into this application.

Conclusion of substantial equivalency:

It is concluded that according with all the test done and information provided that American Dental Products' BONDEASIER SE SYSTEM is substantial equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate product Bisco's "One step".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. George Nicolae
President and Owner
American Dental Products, Incorporated
603-B Country Club Drive
Bensenville, Illinois 60106-1329

APR 13 2010

Re: K093014
Trade/Device Name: American Dental Products BONDEASIER SE SYSTEM
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: April 12, 2010
Received: April 13, 2010

Dear Dr. Nicolae:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093014

Indications for Use Form (Text Version)

Indications for Use

510(k) Number (if known): k 093014
Device Name: American Dental Products BONDEASIER SE SYSTEM
Indications for Use:

As a Universal Self-Etching Adhesive Bonding System, BONDEASIER SE SYSTEM is indicated to be used as an universal dental adhesive to etch, prime and bond to a tooth structure and meth(acrylic) dental composite.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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